

Appl. No. 09/180,657  
Amdt. dated August 19, 2003  
Amendment under 37 CFR 1.116 Expedited  
Procedure Examining Group

PATENT

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-51. (canceled)

52. (currently amended) A method of detecting a lysosomal storage disorder (LSD), monitoring the progress of a LSD or the efficacy of treatment of a LSD in a human or animal subject, the method comprising assaying the level of ~~a LSD marker~~ Lamp-1 (lysosome-associated membrane protein type-1) in a biological sample derived from the subject, wherein the biological sample is a blood, serum, plasma or urine sample; and the LSD marker is selected from the group consisting of Lamp-1 (lysosome-associated membrane protein type-1), 4-sulphatase and ̢-hexosaminidase; and an increase in the level of the ~~LSD marker~~ Lamp-1 in the subject relative to the corresponding level of the ~~LSD marker~~ Lamp-1 in a non-affected individual or population is indicative of a LSD.

53-54. (canceled)

92 2 55. (currently amended) The method according to claim 52, wherein the ~~LSD marker is Lamp-1~~ biological sample is a blood, plasma or urine sample.

56-57. (canceled)

3 58. (previously presented) The method according to claim 52, wherein the biological sample is a blood, plasma, or serum sample.

4 59. (currently amended) The method according to claim 55, wherein the biological sample is a blood, ~~plasma, or serum~~ sample.

5 60. (currently amended) The method according to claim 55, wherein the biological sample is a ~~blood, plasma or urinc~~ sample.

61-62. (canceled)

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6 ~~63~~. (previously presented) The method according to claim ~~52~~<sup>1</sup>, wherein the LSD is selected from the list set forth in Table 1.

7 ~~64~~. (previously presented) The method according to claim ~~63~~<sup>6</sup>, wherein the LSD is selected from the group consisting of MPS I, MPS II, Gaucher disease, Pompe disease and Salla's disease.

8 ~~65~~. (currently amended) The method according to claim ~~52~~<sup>1</sup>, wherein the step of assaying the level of a ~~LSD marker~~ Lamp-1 comprises measuring the enzyme activity of said ~~LSD marker~~ Lamp-1 in the biological sample.

9 ~~66~~. (currently amended) The method according to claim ~~52~~<sup>1</sup>, wherein the step of assaying the level of the ~~LSD marker~~ Lamp-1 comprises contacting the biological sample with one or more antibodies specific for the ~~LSD marker~~ Lamp-1 for a time and under conditions sufficient for the ~~formulation~~ formation of a complex to occur.

9<sub>2</sub>  
[ 67. (canceled)

10 ~~68~~. (previously presented) The method according to claim ~~66~~<sup>9</sup>, wherein the one or more antibodies are monoclonal antibodies.

11 ~~69~~. (previously presented) The method according to claim ~~66~~<sup>9</sup>, wherein the one or more antibodies is/are labeled with a reporter molecule.

12 ~~70~~. (currently amended) The method according to claim ~~66~~<sup>9</sup>, further comprising the step of contacting the complex formed between the ~~LSD marker~~ Lamp-1 and one of the one or more antibodies with a labeled antibody for a time and under conditions sufficient for binding to occur.

13 ~~71~~. (previously presented) The method according to claim ~~70~~<sup>12</sup>, wherein the labeled antibody is labeled with a reporter molecule.

14 ~~72~~. (previously presented) The method according to claim ~~69~~<sup>11</sup>, wherein the reporter molecule is an enzyme, a fluorophore or a radionuclide molecule.

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15 ~~73~~. (previously presented) The method according to claim ~~72~~, wherein the enzyme, fluorophore or radionuclide molecule is selected from the group consisting of horseradish peroxidase, glucose oxidase,  $\beta$ -galactosidase, alkaline phosphatase, fluorescein,  $\text{Eu}^{3+}$  and other lanthanide metals, and rhodamine.

16 ~~74~~. (currently amended) The method according to claim ~~52~~, wherein  
(a) the LSD is selected from the list set forth in Table 1;  
(b) ~~the LSD marker is LAMP-1;~~  
(c) the subject is a human; and  
(d) the biological sample is a human blood, plasma or urine sample.

[75-92. (canceled)]

9<sub>2</sub> 17 ~~93~~. (previously presented) A method for detecting a lysosomal storage disorder (LSD), comprising assaying LAMP-1 (lysosome-associated membrane protein type-1) in a sample of blood obtained from a patient that is asymptomatic for a LSD, an increase in the level of LAMP-1 in the patient relative to the corresponding level of LAMP-1 in a non-affected individual or population being indicative of a LSD.

[94. (canceled).]

18 ~~95~~. (currently amended) A method of detecting a lysosomal storage disorder (LSD), monitoring the progress of a LSD or the efficacy of treatment of a LSD in a human or animal subject, the method comprising assaying the level of a LSD marker Lamp-1 in a biological sample derived from the subject, wherein

~~the LSD marker is selected from the group consisting of Lamp-1 (lysosome-associated membrane protein type-1), 4-sulphatase and  $\beta$ -hexosaminidase;~~

the LSD is selected from the group consisting of Galactosialidosis, Gaucher disease, CM1-gangliosidosis,  $\alpha$ -Mannosidosis, Mucopolysaccharidosis (MPS) I, MPS II, MPS IIIA, MPS IIIB, MPS IIIC, MPS IIID, MPS IVA, MPS VI, Multiple sulphatase deficiency, Sandhoff disease, Sialic Acid Storage disease, Tay-Sachs disease, Wolman disease and Salla's disease; and

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an increase in the level of the ~~LSD marker~~ Lamp-1 in the subject relative to the corresponding level of the LSD marker in a non-affected individual or population is indicative of a LSD.

96. (canceled)

<sup>14</sup> ~~97.~~ <sup>18</sup> (previously presented) The method of claim ~~95~~, wherein the LSD is selected from the group consisting of MPS I, MPS II, Gaucher disease, Pompe disease, and Salla's disease.

<sup>20</sup> ~~98.~~ <sup>18</sup> (previously presented) The method according to claim ~~95~~, wherein the biological sample comprises blood, plasma, serum, urine, a fibroblast cell, a fibroblast cell culture or a fibroblast cellular extract.

<sup>24</sup> ~~99.~~ <sup>20</sup> (previously presented) The method according to claim ~~98~~, wherein the fibroblast cell, fibroblast cell culture or fibroblast cellular extract is a Pompe, Salla, MPS II or MPS VI fibroblast cell, cell culture or cellular extract.

<sup>22</sup> ~~100.~~ <sup>20</sup> (previously presented) The method according to claim ~~98~~, wherein the biological sample is a blood, plasma, serum or urine sample.

<sup>23</sup> ~~101.~~ <sup>18</sup> <sup>45</sup> (previously presented) The method according to claim ~~96~~, wherein the subject is a human.

<sup>24</sup> ~~102.~~ (currently amended) A method of detecting a lysosomal storage disorder (LSD), monitoring the progress of a LSD or the efficacy of treatment of a LSD in a human or animal subject, the method comprising assaying the level of Lamp-2 (lysosome-associated membrane protein type-2) in a biological sample derived from the subject, wherein the LSD is selected from the group consisting of Pompe disease, Gaucher disease and a Mucopolysaccharidosis (MPS) disease; and

an increase in the level of the ~~LSD marker~~ Lamp-2 in the subject relative to the corresponding level of the ~~LSD marker~~ Lamp-2 in a non-affected individual or population is indicative of a LSD.

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25 103. (previously presented) The method of claim 24 102, wherein the LSD is  
Gaucher disease or MPS I.

92 26 104. (previously presented) The method of claim 24 102, wherein the biological  
sample comprises blood, plasma, serum, urine, a fibroblast cell, a fibroblast cell culture or a  
fibroblast cellular extract.

27 105. (previously presented) The method according to claim 26 104, wherein the  
biological sample is a blood, plasma, serum or urine sample.

28 106. (previously presented) The method according to claim 24 102, wherein the  
subject is a human and the biological sample is a human blood, plasma, serum or urine sample.